

# **Exhibit 4**

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 10-Q**

☒ **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
for the quarterly period ended March 30, 2014**

or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
for the transition period from to**

**Commission file number 1-3215**



(Exact name of registrant as specified in its charter)

NEW JERSEY  
(State or other jurisdiction of  
incorporation or organization)

22-1024240  
(I.R.S. Employer  
Identification No.)

One Johnson & Johnson Plaza  
New Brunswick, New Jersey 08933  
(Address of principal executive offices)

Registrant's telephone number, including area code (732) 524-0400

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒      Accelerated filer ☐      Non-accelerated filer ☐      Smaller reporting company ☐  
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

On April 25, 2014 2,829,099,753 shares of Common Stock, \$1.00 par value, were outstanding.

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## JOHNSON &amp; JOHNSON AND SUBSIDIARIES

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## NOTE 11 — LEGAL PROCEEDINGS

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business.

The Company records accruals for such contingencies when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of March 30, 2014, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to determine an estimate of the possible loss or range of loss beyond the amounts already accrued. These matters can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution in any reporting period of one or more of these matters, either alone or in the aggregate, may have a material adverse effect on the Company's results of operations and cash flows for that period.

### **PRODUCT LIABILITY**

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While these subsidiaries believe they have substantial defenses, it is not feasible to predict the ultimate outcome of litigation. The Company has established product liability accruals in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include the ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, the PINNACLE® Acetabular Cup System, pelvic meshes, and RISPERDAL®. As of March 30, 2014, in the U.S. there were approximately 12,500 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, 6,000 with respect to the PINNACLE® Acetabular Cup System, 31,500 with respect to pelvic meshes, and 580 with respect to RISPERDAL®.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson, and the number of pending lawsuits continues to increase. Cases filed in Federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada and Australia. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR™ Hip System plaintiffs to establish a program to settle claims with eligible ASR patients in the United States who had surgery to replace their ASR hip, known as revision surgery, as of August 31, 2013. The U.S. settlement is valued at approximately \$2.5 billion, based on an estimate of 8,000 patients participating in the program. This settlement program is expected to bring to a close significant ASR litigation activity in the U.S. However, many lawsuits in the U.S. will remain; and the settlement program does not address litigation outside of the U.S. The Company continues to receive information with respect to potential costs associated with this recall on a worldwide basis. Updates to existing accruals associated with the ASR may be required in the future as additional information becomes available.

Claims for personal injury have also been made against DePuy and Johnson & Johnson relating to DePuy's PINNACLE® Acetabular Cup System used in hip replacement surgery. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in Federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. The Company has established a product liability accrual in anticipation of product

liability litigation associated with DePuy's PINNACLE<sup>®</sup> Acetabular Cup System. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in Federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Southern District of West Virginia. In addition, class actions and individual personal injury cases or claims have been commenced in Australia, Belgium, Canada, England, Israel, Italy, the Netherlands, Scotland and Venezuela, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. The Company has established a product liability accrual in anticipation of product liability litigation associated with Ethicon's pelvic mesh products. Changes to this accrual may be required in the future as additional information becomes available.

## **INTELLECTUAL PROPERTY**

Certain subsidiaries of Johnson & Johnson are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their business. Many of these matters involve challenges to the coverage and/or validity of the patents on various products. Although these subsidiaries believe that they have substantial defenses to these challenges with respect to all material patents, there can be no assurance as to the outcome of these matters, and a loss in any of these cases could potentially adversely affect the ability of these subsidiaries to sell their products, or require the payment of past damages and future royalties. The most significant of these matters are described below.

### **Medical Devices and Diagnostics**

In January 2010, Tyco Healthcare Group, LP (Tyco) and U.S. Surgical Corporation (now Covidien plc) filed a lawsuit against Ethicon Endo-Surgery, Inc. (EES) in the United States District Court for the District of Connecticut alleging that several features of EES's HARMONIC<sup>®</sup> Scalpel infringed three Tyco patents. The case was tried in July 2012, and in March 2013, the Court ruled that EES's HARMONIC<sup>®</sup> Scalpel infringed Tyco's patents and ordered EES to pay damages of approximately \$176 million, but declined to order injunctive relief. EES has appealed the decision to the United States Court of Appeals for the Federal Circuit. The Company believes EES has strong arguments supporting its appeal. Because the Company believes that the potential for an unfavorable outcome is not probable, it has not established an accrual with respect to the case.

In November 2007, Roche Diagnostics Operations, Inc., et al. (Roche) filed a patent infringement lawsuit against LifeScan, Inc. (LifeScan) in the United States District Court for the District of Delaware, alleging LifeScan's OneTouch<sup>®</sup> line of blood glucose monitoring systems infringe two patents related to the use of microelectrode sensors. In September 2009, LifeScan obtained a favorable ruling on claim construction that precluded a finding of infringement. The Court entered judgment against Roche in July 2010 and Roche appealed. The Court of Appeals reversed the District Court's ruling on claim construction and remanded the case to the District Court for new findings on the issue. Roche is seeking monetary damages and injunctive relief.

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVC) in the United States District Court for the Eastern District of Texas alleging that JJVC's manufacture and sale of its ACUVUE<sup>®</sup> ADVANCE<sup>®</sup> and ACUVUE<sup>®</sup> OASYS<sup>®</sup> Hydrogel Contact Lenses infringe their U.S. Patent No. 5,712,327 (the Chang patent). Rembrandt is seeking monetary relief. The case was transferred to the United States District Court for the Middle District of Florida. In May 2012, the jury returned a verdict holding that neither of the accused lenses infringes the '327 patent. Rembrandt appealed, and in August 2013, the United States Court of Appeals for the Federal Circuit affirmed the District Court's judgment. Rembrandt has asked the District Court to grant it a new trial based on alleged new evidence, and the Court's decision on that motion is pending.

In December 2009, the State of Israel filed a lawsuit in the District Court in Tel Aviv Jaffa against Omrix Biopharmaceuticals, Inc. and various affiliates (Omrix). In the lawsuit, the State claims that an employee of a government-owned hospital was the inventor on several patents related to fibrin glue technology that the employee developed while he was a government employee. The State claims that he had no right to transfer any intellectual property to Omrix because it belongs to the State. The State is seeking damages plus royalties on QUIXIL<sup>™</sup> and EVICEL<sup>™</sup> products, or alternatively, transfer of the patents to the State.

In September 2011, LifeScan, Inc. (LifeScan) filed a lawsuit against Shasta Technologies, Instacare Corp and Conductive Technologies (collectively, Shasta) in the United States District Court for the Northern District of California for patent infringement for the making and marketing of a strip for use in LifeScan's OneTouch<sup>®</sup> Blood Glucose Meters. Shasta has alleged that the three LifeScan patents-in-suit are invalid. Shasta also challenged the validity of the asserted patents in the U.S.

Patent and Trademark Office (USPTO) and the patent infringement case has been stayed pending the outcome of the validity proceedings. The validity of two of the patents was confirmed by the USPTO and a decision regarding the validity of the third patent is pending. In April 2013, Shasta brought counterclaims for antitrust violations and false advertising and those claims have been stayed pending resolution of the patent infringement case.

In November 2011, Howmedica Osteonics Corp. (Howmedica) and Stryker Ireland Ltd. (Stryker) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. (DePuy) in the United States District Court for the District of New Jersey alleging infringement by DePuy's PINNACLE<sup>®</sup> Acetabular Cup System and DURALOC<sup>®</sup> Acetabular Cup System of a patent relating to a dual-locking mechanism feature in an acetabular cup system. Howmedica and Stryker are seeking monetary damages and injunctive relief. DePuy filed a counterclaim in February 2012 asserting that Stryker's Trident Acetabular Hip System infringes DePuy's U.S. Patent No. 6,610,097. DePuy is seeking damages and injunctive relief.

In May 2012, Medtronic MiniMed, Inc., Medtronic Puerto Rico Operations Co. and MiniMed Distribution Corp. (collectively, Medtronic MiniMed) filed a patent infringement lawsuit against Animas Corporation in the United States District Court for the Central District of California alleging that Animas' OneTouch<sup>®</sup> Ping<sup>®</sup> Glucose Management System and the IR 1250, IR 2020 and IR 2000 insulin pumps infringe nine of their patents. Medtronic MiniMed since withdrew two of the patents from the lawsuit and is seeking monetary damages and injunctive relief with respect to the remaining patents. Trial is scheduled for September 2014.

In March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that all of Cordis's sales of the CYPHER<sup>®</sup> and CYPHER SELECT<sup>®</sup> Stents made in the United States since 2005 willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Medinol is seeking damages and attorney's fees. After trial in January 2014, the District Court dismissed the case, finding Medinol unreasonably delayed bringing its claims. Medinol may appeal to the United States Court of Appeals for the Federal Circuit.

In January 2014, Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare S.A. (collectively, Baxter) filed a lawsuit against Johnson & Johnson, Ethicon, Inc. (Ethicon), Ferrosan Medical Devices A/S and Packaging Coordinators Inc. in the United States District Court for the Northern District of Illinois, alleging that the manufacture, importation, sale and/or use of Ethicon's SURGIFLO<sup>®</sup> Hemostatic Matrix family of products infringes six of Baxter's patents. Baxter is seeking monetary damages and injunctive relief. In February 2014, Baxter also filed a complaint before the United States International Trade Commission against the same defendants alleging that the importation into the United States of Ethicon's SURGIFLO<sup>®</sup> Hemostatic Matrix family of products violates Section 337 of the Tariff Act of 1930 due to the alleged patent infringement, and is seeking an exclusion order to enjoin the importation into the United States of such products.

#### Pharmaceutical

In May 2009, Abbott Biotechnology Ltd. (Abbott) filed a patent infringement lawsuit against Centocor, Inc. (Centocor) (now Janssen Biotech, Inc. (JBI)) in the United States District Court for the District of Massachusetts alleging that SIMPONI<sup>®</sup> infringes Abbott's U.S. Patent Nos. 7,223,394 and 7,541,031 (the Salfeld patents). Abbott is seeking monetary damages and injunctive relief. Summary judgment motions were decided and the parties are awaiting a trial date.

In August 2009, Abbott GmbH & Co. (Abbott GmbH) and Abbott Bioresearch Center filed a patent infringement lawsuit against Centocor (now JBI) in the United States District Court for the District of Massachusetts alleging that STELARA<sup>®</sup> infringes two United States patents assigned to Abbott GmbH. JBI filed a complaint in the United States District Court for the District of Columbia for a declaratory judgment of non-infringement and invalidity of the Abbott GmbH patents, as well as a Complaint for Review of a Patent Interference Decision that granted priority of invention on one of the two asserted patents to Abbott GmbH. The cases have been transferred from the District of Columbia to the District of Massachusetts. Trial was held in September 2012 and a jury returned a verdict in favor of JBI, invalidating Abbott's patent claims. In March 2013, the Court denied Abbott's post-trial motions challenging the outcome and granted JBI's motion on the appeal of the interference decision. Abbott appealed, and oral argument was held in March 2014 in the Court of Appeals for the Federal Circuit. Also in August 2009, Abbott GmbH and Abbott Laboratories Limited brought a patent infringement lawsuit in The Federal Court of Canada alleging that STELARA<sup>®</sup> infringes Abbott GmbH's Canadian patent. A trial was held in December 2013 in the Canadian case. In January 2014, the Court ruled in favor of Abbott, finding that the asserted claims were valid and infringed by STELARA<sup>®</sup>. JBI has appealed that decision. The Company believes JBI has strong arguments supporting its appeal. A trial on Abbott's motion for an injunction is scheduled for May 2014. In addition to the U.S. and Canadian litigations, in August 2012, Abbott filed patent infringement lawsuits related to STELARA<sup>®</sup> in the Netherlands, Switzerland and Germany. In each of these cases, briefing has been commenced or recently completed and hearings on the merits will take place later this year or early in 2015. In each of the above cases, Abbott is seeking monetary damages and injunctive relief.



In March 2012, Noramco, Inc. (Noramco), a subsidiary of Johnson & Johnson, moved to intervene in three patent infringement lawsuits filed in the United States District Court for the Southern District of New York (SDNY) by Purdue Pharma L.P. and others (Purdue) against Noramco oxycodone customers, Impax Laboratories, Inc. (Impax), Teva Pharmaceuticals USA, Inc. (Teva) and Amneal Pharmaceuticals, LLC (Amneal). In February 2013, Noramco appeared on behalf of Noramco customers Watson Laboratories, Inc.- Florida and Andrx Labs, LLC (collectively, Watson/Andrx) in a similar lawsuit filed by Purdue in the SDNY. The lawsuits are in response to the defendants' respective Abbreviated New Drug Applications seeking approval to market generic extended release oxycodone products before the expiration of certain Purdue patents. Three of the asserted patents relate to oxycodone and processes for making oxycodone, and Noramco has agreed to defend the lawsuits on behalf of Impax, Teva, Amneal and Watson/Andrx. In April 2013, Watson/Andrx entered into a confidential settlement with Purdue. The trial against Impax and Teva (as well as two parties not defended by Noramco) took place in September 2013, and Noramco defended Teva and Impax. In November 2013, Impax entered into a confidential settlement with Purdue. In January 2014, the Court issued a decision invalidating the relevant Purdue patents. Purdue has appealed the decision.

In August 2012, Dr. James M. Swanson filed a lawsuit against ALZA Corporation (ALZA) in the Northern District of California seeking to be added as an inventor on three ALZA-owned patents relating to CONCERTA<sup>®</sup>. Alternatively, Dr. Swanson has alleged, among other things, that the patents-in-suit are invalid and/or unenforceable as a result of ALZA's alleged omission of Dr. Swanson as a named inventor on the patents. The lawsuit also includes claims of fraud, breach of fiduciary duty and unfair competition. Dr. Swanson is seeking damages and an award of unjust enrichment. ALZA filed a motion to dismiss Dr. Swanson's claims, as well as counterclaims for breach of contract and negligent misrepresentation. The Court granted the motion in part, and denied it in part. Discovery in the case is ongoing.

Johnson & Johnson acquired the prostate cancer business of Aragon Pharmaceuticals, Inc. (Aragon), including ARN-509, a compound being tested for treatment of prostate cancer, in September 2013. Prior to the acquisition, in May 2011, Medivation, Inc. (Medivation) had sued Aragon and the University of California seeking rights to ARN-509. In December 2012, the State Court granted summary judgment to Aragon on Medivation's claims, awarding the rights of the ARN-509 compound to Aragon, and in January 2013, the Court dismissed the case against Aragon. Medivation has appealed the summary judgment rulings.

#### REMICADE<sup>®</sup> Related Cases

In March 2013, Hospira Healthcare Corporation (Hospira) filed an impeachment proceeding against The Kennedy Institute of Rheumatology (Kennedy) challenging the validity of a Canadian patent related to REMICADE<sup>®</sup> (a Feldman patent), which is exclusively licensed to Janssen Biotech, Inc. (JBI). In October 2013, Kennedy, along with JBI, Janssen Inc. and Cilag GmbH International (both affiliates of JBI), filed a counterclaim for infringement against Celltrion Healthcare Co., Ltd., Celltrion Inc. (together, Celltrion) and Hospira. The counterclaim alleges that the products described in Celltrion's and Hospira's marketing applications to Health Canada for their subsequent entry biologics (SEB) to REMICADE<sup>®</sup> would infringe the Feldman patents owned by Kennedy. In January 2014, Health Canada approved Celltrion's and Hospira's SEBs to REMICADE<sup>®</sup>, allowing Celltrion and Hospira to market their biosimilar versions of REMICADE<sup>®</sup> in Canada, regardless of the pending patent action. Discovery in the patent action has commenced.

In September 2013, JBI and New York University Medical Center (NYU) received an Office Action from the United States Patent Office rejecting the claims in U.S. Patent No. 6,284,471 relating to REMICADE<sup>®</sup> (the '471 patent) in a reexamination proceeding instituted by a third party. The '471 patent is co-owned by JBI and NYU, and NYU granted JBI an exclusive license to NYU's rights under the patent. Currently, the '471 patent in the United States expires in September 2018. JBI believes the '471 patent is valid and has responded to the Office Action to defend the patent, and if necessary, will pursue available appeals.

In March 2014, Celltrion filed a declaratory judgment lawsuit against JBI in the United States District Court for the District of Massachusetts seeking to invalidate the '471 patent and two other U.S. patents that relate to REMICADE<sup>®</sup> and are co-owned by JBI and NYU, and exclusively licensed to JBI (collectively, the Le patents). Also in March 2014, Celltrion filed a lawsuit in the United States District Court for the Southern District of New York against Kennedy seeking to invalidate three patents owned by Kennedy (the Feldman patents). The Feldman patents are licensed to JBI and also relate to REMICADE<sup>®</sup>. Celltrion alleges that it will be seeking FDA approval to make and sell its own biosimilar version of REMICADE<sup>®</sup>.

If any of the Le or Feldman patents is found to be invalid, any such patent could not be relied upon to prevent the introduction of biosimilar versions of REMICADE<sup>®</sup>. The timing of the possible introduction of a biosimilar version of REMICADE<sup>®</sup> in the United States would be subject to approval by the FDA. If a biosimilar version of REMICADE<sup>®</sup> were to be approved and introduced to the market, loss of exclusivity would likely result in a reduction in sales.

## Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed Abbreviated New Drug Applications (ANDAs) with the FDA seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement, invalidity and unenforceability of the applicable patents. In the event the subsidiaries are not successful in these actions, or the statutory 30-month stays of the ANDAs expire before the United States District Court rulings are obtained, the third-party companies involved will have the ability, upon approval of the FDA, to introduce generic versions of the products at issue, resulting in very substantial market share and revenue losses for those products.

### PREZISTA<sup>®</sup>

A number of generic companies have filed ANDAs seeking approval to market generic versions of PREZISTA<sup>®</sup>. In November 2010, Tibotec, Inc. (now Tibotec, LLC) and Tibotec Pharmaceuticals (now Janssen R&D Ireland) (collectively, Tibotec) filed a patent infringement lawsuit against Lupin, Ltd., Lupin Pharmaceuticals, Inc. (collectively, Lupin), Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan) in the United States District Court for the District of New Jersey in response to Lupin's and Mylan's respective ANDAs seeking approval to market generic versions of Tibotec's PREZISTA<sup>®</sup> product before the expiration of Tibotec's patent relating to PREZISTA<sup>®</sup>. Lupin and Mylan each filed counterclaims alleging non-infringement and invalidity. In July 2011, Tibotec filed another patent infringement lawsuit against Lupin in the United States District Court for the District of New Jersey in response to Lupin's supplement to its ANDA to add new dosage strengths for its proposed product. In August 2011, Tibotec and G.D. Searle & Company (G.D. Searle) filed a patent infringement lawsuit against Lupin and Mylan in response to their notice letters advising that their ANDAs are seeking approval to market generic versions of Tibotec's PREZISTA<sup>®</sup> product before the expiration of two additional patents relating to PREZISTA<sup>®</sup> that Tibotec exclusively licenses from G.D. Searle.

In September 2011, the Court consolidated the above lawsuits. The approved New Drug Application for PREZISTA<sup>®</sup> was transferred from Tibotec, Inc. to Janssen Products, LP in December 2011, and in 2012 and 2013, Janssen Products, LP and Janssen R&D Ireland (collectively, Janssen) added several patents that they own or exclusively license from G.D. Searle to the consolidated action against Mylan and Lupin.

In March 2013, Janssen filed a patent infringement lawsuit against Hetero Drugs, Ltd. Unit III and Hetero USA Inc. in the United States District Court for the District of New Jersey, alleging infringement of United States Patent Nos. 7,126,015 and 7,595,408.

In May 2013, Lupin notified Janssen that it filed an ANDA seeking approval to market a new dosage strength of its generic version of PREZISTA<sup>®</sup>. In response, Janssen filed a patent infringement lawsuit in the United States District Court for the District of New Jersey, alleging that Lupin's new dosage strength would infringe the same patents that Janssen is asserting against Lupin in the original action.

In June 2013, Janssen and G.D. Searle dismissed their claims relating to the patents owned by G.D. Searle against Lupin and Mylan, based on those parties' agreement not to seek FDA approval of their respective ANDAs until the November 2017 expiration of the G.D. Searle patents. A trial regarding the remaining patents in the consolidated action was completed in April 2014, and the parties are awaiting a decision.

Tibotec and G.D. Searle also filed patent infringement lawsuits against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals, Ltd. (collectively, Teva) in the United States District Court for the District of New Jersey in response to Teva's ANDA seeking approval to market a generic version of PREZISTA<sup>®</sup> before the expiration of certain patents relating to PREZISTA<sup>®</sup> that Tibotec either owns or exclusively licenses from G.D. Searle. In March 2014, the parties entered into a confidential settlement agreement and the lawsuits against Teva were dismissed.

In each of the above lawsuits, Tibotec and Janssen sought or are seeking an Order enjoining the defendants from marketing their generic versions of PREZISTA<sup>®</sup> before the expiration of the relevant patents.

### CONCERTA<sup>®</sup>

In June 2013, ALZA Corporation and Janssen Pharmaceuticals, Inc. (collectively, Janssen) filed patent infringement lawsuits in the District Court for the District of Delaware against Par Pharmaceuticals, Inc., Osmotica Kereskedelmies Szolgálat Kft (Osmotica), and Norwich Pharmaceuticals, Inc. (Norwich) in response to those parties' ANDAs seeking approval to market a generic version of CONCERTA<sup>®</sup> before the expiration of United States Patent No. 8,163,798 (the '798 patent). In addition, in



September 2013, Par and Osmotica filed counterclaims against Janssen seeking declarations of invalidity and noninfringement of the patent-in-suit, and Norwich filed a motion to dismiss. Norwich was dismissed from the case in October 2013 based on its agreement to be bound by the outcome of the case. In March 2014, Janssen amended its complaint against Par and Osmotic to assert infringement of newly issued United States Patent No. 8,629,179 (the '179 patent). In each of the above lawsuits, Janssen is seeking an Order enjoining the defendants from marketing their generic versions of CONCERTA ® before the expiration of the '798 and '179 patents.

#### NUCYNTA ® AND NUCYNTA ® ER

In July 2013, Janssen Pharmaceuticals, Inc. (JPI) filed patent infringement lawsuits in the United States District Court for the District of New Jersey against Actavis Elizabeth LLC, Actavis Inc. and Actavis LLC (collectively, Actavis), as well as Alkem Laboratories Limited and Ascend Laboratories, LLC (collectively, Alkem). The patent infringement claims against Actavis and Alkem relate to their respective ANDAs seeking approval to market a generic version of NUCYNTA ® ER before the expiration of United States Reissue Patent No. 39,593 (the '593 patent), United States Patent No. 7,994,364 (the '364 patent) and, as to Actavis only, United States Patent No. 8,309,060 (the '060 patent). The lawsuit also includes a patent infringement claim against Alkem in response to its ANDA seeking approval to market a generic version of NUCYNTA ® before the expiration of the '593 and '364 patents. JPI is seeking an Order enjoining the defendants from marketing their generic versions of NUCYNTA ® ER and NUCYNTA ® before the expiration of the asserted patents. In October 2013, JPI received a Paragraph IV Notice from Sandoz, Inc. with respect to NUCYNTA ® related to the '364 patent, and a Paragraph IV Notice from Roxane Laboratories, Inc. (Roxane) with respect to NUCYNTA ® related to the '593 and '364 patents and United States Patent No. 6,071,970. In response to those notices, JPI filed an additional complaint in the United States District Court for the District of New Jersey against Roxane and Sandoz asserting the '364 patent against Sandoz and the '364 and '593 patents against Roxane. In December 2013, JPI filed an additional complaint in the District Court of New Jersey against Alkem asserting United States Patent No. 8,536,130 related to its ANDA seeking approval to market a generic version of NUCYNTA ® ER.

#### **GOVERNMENT PROCEEDINGS**

Like other companies in the pharmaceutical and medical devices and diagnostics industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. As a result, interaction with government agencies is ongoing. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

#### **Average Wholesale Price (AWP) Litigation**

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, are defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWP's in calculating provider reimbursement levels. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a Multi-District Litigation (MDL) in the United States District Court for the District of Massachusetts.

The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. In June 2007, after a trial on the merits, the MDL Court dismissed the claims of two of the plaintiff classes against the J&J AWP Defendants. In March 2011, the Court dismissed the claims of the third class against the J&J AWP Defendants without prejudice.

AWP cases brought by various Attorneys General have proceeded to trial against other manufacturers. Several state cases against certain subsidiaries of Johnson & Johnson have been settled, including the case in Alaska, which settled in April 2014, and a few state cases are still pending. The AWP case filed by the Attorney General of Illinois is set for trial in September 2014. In addition, an AWP case against the J&J AWP Defendants brought by the Attorney General of the Commonwealth of Pennsylvania was tried in Commonwealth Court in October and November 2010. The Court found in the Commonwealth's favor with regard to certain of its claims under the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPL"), entered an injunction, and awarded \$45 million in restitution and \$6.5 million in civil penalties. The Court found in the J&J AWP Defendants' favor on the Commonwealth's claims of unjust enrichment, misrepresentation/fraud, civil conspiracy, and on certain of the Commonwealth's claims under the UTPL. The J&J AWP Defendants have appealed the Commonwealth

Court's UTPL ruling to the Pennsylvania Supreme Court. The Company believes that the J&J AWP Defendants have strong arguments supporting their appeal. Because the Company believes that the potential for an unfavorable outcome is not probable, it has not established an accrual with respect to the verdict.

### RISPERDAL®

In November 2013, Johnson & Johnson and its subsidiary, Janssen Pharmaceuticals, Inc. (JPI), finalized previously disclosed settlement agreements with the United States Department of Justice and forty-five states resolving federal investigations and state Medicaid claims related to past promotional practices of RISPERDAL® from 1999 through 2005, and other matters. JPI had also settled alleged consumer fraud claims in connection with the sale and marketing of RISPERDAL® with thirty-six states and the District of Columbia in September 2012. In addition to these actions, the Attorneys General of several states brought actions against JPI, related to the sale and marketing of RISPERDAL®, seeking one or more of the following remedies: reimbursement of Medicaid or other public funds for RISPERDAL® prescriptions written for off-label use, compensation for treating their citizens for alleged adverse reactions to RISPERDAL®, civil fines or penalties for violations of state false claims acts or consumer fraud statutes, punitive damages, or other relief relating to alleged unfair business practices. Certain of these actions also sought injunctive relief relating to the promotion of RISPERDAL®. Many of the actions and claims brought by the state Attorneys General have been settled, either individually or as part of the settlements described above.

Four states have remaining claims in litigation related to RISPERDAL®: one claim is on remand in Arkansas, the case in South Carolina is on appeal, and the cases in Kentucky and Mississippi have not progressed to trial. The Company has not accrued amounts equal to the judgments obtained in Arkansas, Louisiana or South Carolina. To the extent any state has an outstanding Medicaid-related claim not resolved by the settlements referenced above, the Company has accrued an amount approximately equal to what that state would have received if it had participated in the relevant federal settlement. State cases that went to judgment after trial are discussed below.

In 2004, the Attorney General of West Virginia commenced a lawsuit against Janssen Pharmaceutica (now JPI) based on claims of alleged consumer fraud as to DURAGESIC®, as well as RISPERDAL®. JPI was found liable and damages were assessed at \$4.5 million. JPI filed an appeal, and in November 2010, the West Virginia Supreme Court of Appeals reversed the trial court's decision. In December 2010, the Attorney General of West Virginia dismissed the case as it related to RISPERDAL® without any payment. Thereafter, JPI settled the case insofar as it related to DURAGESIC®.

In 2004, the Attorney General of Louisiana filed a multi-count Complaint against Janssen Pharmaceutica (now JPI). Johnson & Johnson was later added as a defendant. The case was tried in October 2010. The issue tried to the jury was whether Johnson & Johnson or JPI had violated the State's Medical Assistance Program Integrity Law (the Act) through misrepresentations allegedly made in the mailing of a November 2003 Dear Health Care Professional letter regarding RISPERDAL®. The jury returned a verdict that JPI and Johnson & Johnson had violated the Act and awarded \$257.7 million in damages. The trial judge subsequently awarded the Attorney General counsel fees and expenses in the amount of \$73 million. In January 2014, the Louisiana Supreme Court reversed the district court's judgment in favor of the Attorney General, and rendered judgment in favor of Johnson & Johnson and JPI. In April 2014, the Louisiana Supreme Court denied the Attorney General's petition seeking a rehearing of the appellate arguments.

In 2007, the Office of General Counsel of the Commonwealth of Pennsylvania filed a lawsuit against Janssen Pharmaceutica (now JPI) on a multi-Count Complaint related to Janssen Pharmaceutica's sale of RISPERDAL® to the Commonwealth's Medicaid program. The trial occurred in June 2010. The trial judge dismissed the case after the close of the plaintiff's evidence. The Commonwealth filed an appeal and in July 2012, the Pennsylvania Appeals Court upheld the dismissal of the Commonwealth's case.

In 2007, the Attorney General of South Carolina filed a lawsuit against Johnson & Johnson and Janssen Pharmaceutica (now JPI) on several counts. In March 2011, the matter was tried to a jury on liability only, at which time the lawsuit was limited to claims of violation of the South Carolina Unfair Trade Practices Act, including, among others, questions of whether Johnson & Johnson or JPI engaged in unfair or deceptive acts or practices in the conduct of any trade or commerce by distributing the November 2003 Dear Health Care Professional letter regarding RISPERDAL® or in their use of the product's FDA-approved label. The jury found in favor of Johnson & Johnson and against JPI. In June 2011, the Court awarded civil penalties of approximately \$327.1 million against JPI. JPI has appealed this judgment and the Company believes it has strong arguments supporting the appeal. Oral argument on the appeal took place before the South Carolina Supreme Court in March 2013, and the parties are awaiting a decision.

In April 2012, in the lawsuit brought by the Attorney General of Arkansas, the jury found against both JPI and Johnson & Johnson, and the Court imposed penalties in the amount of approximately \$1.2 billion. In January 2013, the trial court awarded

attorney fees of approximately \$181 million. JPI and Johnson & Johnson appealed both awards to the Arkansas Supreme Court, and in March 2014, the Arkansas Supreme Court dismissed the State's claim under the Arkansas Medicaid Fraud False Claims Act, as well as the approximately \$1.2 billion in penalties, and reversed and remanded a claim under the Arkansas Deceptive Trade Practices Act. In April 2014, the Arkansas Supreme Court rejected a petition by the State for rehearing on the case.

#### McNeil Consumer Healthcare

Starting in June 2010, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. (McNeil Consumer Healthcare) and certain affiliates, including Johnson & Johnson (the Companies), received grand jury subpoenas from the United States Attorney's Office for the Eastern District of Pennsylvania requesting documents broadly relating to recalls of various products of McNeil Consumer Healthcare, and the FDA inspections of the Fort Washington, Pennsylvania and Lancaster, Pennsylvania manufacturing facilities, as well as certain documents relating to recalls of a small number of products of other subsidiaries. In addition, in February 2011, the government served McNEIL-PPC, Inc. (McNEIL-PPC) with a Civil Investigative Demand seeking records relevant to its investigation to determine if there was a violation of the Federal False Claims Act. The grand jury and False Claims investigations are continuing. The Companies are cooperating with the United States Attorney's Office in responding to these investigations.

The Companies have also received Civil Investigative Demands from multiple State Attorneys General Offices broadly relating to the McNeil recall issues. The Companies continue to cooperate with these inquiries, which are being coordinated through a multi-state coalition. If a resolution cannot be reached with this multi-state coalition, it is possible that individual State Attorneys General Offices may file civil money claims against the Companies. In January 2011, the Oregon Attorney General filed a civil complaint against Johnson & Johnson, McNEIL-PPC and McNeil Healthcare LLC in state court alleging civil violations of the Oregon Unlawful Trade Practices Act relating to an earlier recall of a McNeil OTC product. In November 2012, the state court granted a motion by the Companies to dismiss Oregon's complaint in its entirety, with prejudice. In December 2012, Oregon filed a Notice of Appeal in the Court of Appeals of the State of Oregon. Briefing on the appeal has concluded and the Court has not set a hearing date.

#### Other

In September 2011, Synthes, Inc. (Synthes) received a Civil Investigative Demand issued pursuant to the False Claims Act from the United States Attorney's Office for the Eastern District of Pennsylvania. The Demand sought information regarding allegations that fellowships had been offered to hospitals in exchange for agreements to purchase products. Synthes has produced documents and information in response to the Demand and is cooperating with the inquiry.

In April 2012, Janssen Pharmaceuticals, Inc. (JPI) received a letter requesting certain documents from the United States Department of Justice relating to the marketing and promotion of DORIBAX<sup>®</sup>. In 2012, JPI provided documents and will continue to cooperate with any further inquiries if and when they are received.

In May 2012, Acclarent, Inc. (Acclarent) received a subpoena from the United States Attorney's Office for the District of Massachusetts requesting documents broadly relating to the sales, marketing and alleged off-label promotion by Acclarent of RELIEVA STRATUS<sup>™</sup> MicroFlow Spacer products. The investigation is continuing and Acclarent is cooperating with the United States Attorney's Office in responding to the subpoena.

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now DePuy Synthes, Inc. (DePuy Synthes)), and Johnson & Johnson Services, Inc. received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice for the production of materials relating to the ASR<sup>™</sup> XL Hip device. The government has since made additional informal requests for the production of documents as to the device. The government is investigating whether any person or entity submitted or caused to be submitted false claims or false statements affecting federal health care programs in connection with the marketing and use of the ASR<sup>™</sup> XL Hip device. DePuy Orthopaedics, Inc., DePuy Synthes, and Johnson & Johnson Services, Inc. have voluntarily produced documents in response to the government's informal requests and are fully cooperating with the government's civil investigation. In addition, a group of state Attorneys General has issued Civil Investigative Demands relating to the development, sales and marketing of several of DePuy Orthopaedics, Inc.'s hip products. The Attorney General of Oregon is investigating these matters independently of the other states and has also issued a Civil Investigative Demand.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). Johnson & Johnson and Ethicon have since entered into a tolling agreement with

the 44 states participating in the multi-state investigation and are in the process of responding to Civil Investigative Demands served by certain of the participating states.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of UVADEX<sup>®</sup> (methoxsalen) and the UVAR XTS<sup>®</sup> System during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013. OCD and Johnson & Johnson retain certain liabilities that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014, the United States Attorney's Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with the request. If and when the divestiture of OCD is completed, Johnson & Johnson would retain OCD's portion of any liability that may result from the investigation for activity that occurred prior to the sale of Therakos.

In May 2013, Janssen Pharmaceuticals, Inc. (JPI) received a subpoena from the Atlanta Regional Office of the Department of Health and Human Services, Office of Inspector General, seeking production of documents and information regarding: (1) the sales, marketing and promotional practices, including the remuneration of healthcare providers, related to NUCYNTA<sup>®</sup> IR and NUCYNTA<sup>®</sup> ER; and (2) any studies, reports and/or complaints regarding the safety and/or actual or potential side effects of NUCYNTA<sup>®</sup> IR and NUCYNTA<sup>®</sup> ER. JPI is in the process of responding to the subpoena.

In recent years, Johnson & Johnson has received numerous requests from a variety of United States Congressional Committees to produce information relevant to ongoing congressional inquiries. It is the policy of Johnson & Johnson to cooperate with these inquiries by producing the requested information.

## **GENERAL LITIGATION**

In June 2009, following the public announcement that Ortho-Clinical Diagnostics, Inc. (OCD) had received a grand jury subpoena from the United States Department of Justice, Antitrust Division, in connection with an investigation that has since been closed, multiple class action complaints were filed against OCD by direct purchasers seeking damages for alleged price fixing. These cases were consolidated for pre-trial purposes in the United States District Court for the Eastern District of Pennsylvania as *In re Blood Reagent Antitrust Litigation*. In August 2012, the District Court granted a motion filed by Plaintiffs for class certification. In October 2012, the United States Court of Appeals for the Third Circuit granted OCD's petition for interlocutory review of the class certification ruling. Oral argument on the appeal was held in February 2014 and the parties are awaiting a decision. If and when the divestiture of OCD is completed, Johnson & Johnson would retain any liability that may result from these cases.

In September 2010, a shareholder, Ronald Monk, filed a lawsuit in the United States District Court for the District of New Jersey seeking class certification and alleging that Johnson & Johnson and certain individuals, including executive officers and employees of Johnson & Johnson, failed to disclose that a number of manufacturing facilities failed to maintain current good manufacturing practices, and that as a result, the price of the Company's stock declined significantly. Plaintiff sought to pursue remedies under the Securities Exchange Act of 1934 to recover his alleged economic losses. In December 2011, a motion by Johnson & Johnson to dismiss was granted in part and denied in part. Plaintiff moved the Court to reconsider part of the December 2011 ruling. In May 2012, the Court denied Plaintiff's motion for reconsideration. In September 2012, Plaintiff filed a Second Amended Complaint and Johnson & Johnson and the individual defendants moved to dismiss Plaintiff's Second Amended Complaint in part. Following mediation, the parties reached an agreement in principle to settle the case, and in July 2013, filed for preliminary approval of the proposed settlement. In November 2013, the Court approved the settlement. Three parties that had objected to the settlement have appealed the Court's approval orders. Mediation for the appeal has been scheduled for May 2014.

In April 2011, OMJ Pharmaceuticals, Inc. (OMJ PR) filed a lawsuit against the United States in United States District Court for the District of Puerto Rico alleging overpayment of federal income taxes for the tax years ended November 30, 1999 and November 30, 2000. If OMJ PR loses this lawsuit, it may face liability for subsequent tax years. OMJ PR alleges that the Internal Revenue Service erroneously calculated OMJ PR's tax credits under Section 936 of the Tax Code. OMJ PR filed a motion for summary judgment, and the United States filed a cross motion for summary judgment. In October 2012, the Court granted a motion by the United States for summary judgment and denied a motion by OMJ PR for summary judgment. OMJ PR has appealed this decision. Oral argument was held in November 2013, and the parties are awaiting a decision.



In September 2011, Johnson & Johnson, Johnson & Johnson Inc. and McNeil Consumer Healthcare Division of Johnson & Johnson Inc. received a Notice of Civil Claim filed by Nick Field in the Supreme Court of British Columbia, Canada (the BC Civil Claim). The BC Civil Claim is a putative class action brought on behalf of persons who reside in British Columbia and who purchased during the period between September 20, 2001 and in or about December 2010 one or more various McNeil infants' or children's over-the-counter medicines that were manufactured at the Fort Washington facility. The BC Civil Claim alleges that the defendants violated the BC Business Practices and Consumer Protection Act, and other Canadian statutes and common laws, by selling medicines that were allegedly not safe and/or effective or did not comply with Canadian Good Manufacturing Practices. The class certification hearing is currently not scheduled.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

#### Shareholder Derivative Action

In September 2011, two shareholder derivative lawsuits were filed in the United States District Court for the District of New Jersey by Donovan Spamer and The George Leon Family Trust naming current and former directors of Johnson & Johnson as defendants and Johnson & Johnson as the nominal defendant. These lawsuits allege that the defendants breached their fiduciary duties in their decisions with respect to the compensation of the Chief Executive Officer during the period from 2008 through 2011, and that the defendants made misleading statements in the Company's annual proxy statements. Both of these lawsuits were voluntarily dismissed without prejudice, but a similar lawsuit, The George Leon Family Trust v. Coleman, was refiled in July 2012. That lawsuit seeks a variety of relief, including monetary damages, injunctive relief, and corporate governance reforms. In June 2013, the Board of Directors of Johnson & Johnson (the Board) received a report prepared by special, independent counsel to the Board, which investigated the allegations contained in the derivative actions filed by Donovan Spamer and by The George Leon Family Trust, and in several shareholder demand letters that the Board received in 2011 and 2012 raising similar issues. The report recommended that Johnson & Johnson reject the shareholder demands and take whatever steps are necessary or appropriate to secure dismissal of the derivative litigation. The Board unanimously adopted the report's recommendations.

In September 2013, Johnson & Johnson moved to dismiss or, in the alternative, for summary judgment in The George Leon Family Trust v. Coleman, based upon the Board's determination. In October 2013, the plaintiff in the Leon litigation filed an amended complaint and Johnson & Johnson moved to dismiss the amended complaint or, in the alternative, for summary judgment, based upon the Board's determination. This motion was argued in March 2014, and a decision is pending.